## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

n re Application of:

Fine et al.

al No:

09/787,325

June 4, 2001

For:

Combinations of Chromium or Vanadium with Antidiabetics for Glucose Metabolism Diseases Examiner:

Criares, T.

Art Unit:

1617

Attorney Docket No.

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TECH CENTER 1600/2900

## CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria,

VA 22313-1450

Date

John Barretto

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

5,2003

Sir:

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 (c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449.

This Information Disclosure Statement is being submitted after the events recited in 37 C.F.R. § 1.97 (b). The Commissioner is therefore authorized to charge the fee set forth in § 1.17 (p) to our **Deposit Account No. 06-1448**, reference AKT-053.02.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

Documents A1 through A3 were not previously cited, and full copies of such documents are provided herewith. Applicants note that Documents C1 through C11 have been previously cited.

The present Supplemental Information Disclosure Statement simply provides information about

Documents C1 through C11, such as a date or more complete citation, that Examiner noted was

missing in the Office Action mailed June 2, 2003. No copies of Documents C1 through C11

have been provided.

This submission does not represent that a search has been made or that no better art exists

and does not constitute an admission that each or all of the listed documents are material or

constitute "prior art." If the Examiner applies any of the documents as prior art against any

claim in the application and Applicants determine that the cited documents do not constitute

"prior art" under United States law, Applicants reserve the right to present to the Office the

relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability

of the disclosed invention over the listed documents, should one or more of the documents be

applied against the claims of the present application.

If there are any additional fees due in connection with this submission, the Commissioner

is authorized to charge any deficiencies or credit any overpayment to/from our **Deposit Account** 

No. 06-1448, reference AKT-053.02

Date: December 3, 2003

Customer No: 25181

Patent Group

Foley Hoag LLP

155 Seaport Blvd.

Boston, MA 02210-2600

Phone: (617) 832-1000

Fax: (617) 832-7000

Respectfully Submitted, FOLÉY/HOAG LLP

Jennifer A/Zarutskie, Ph.D.

Rég/No. 50.55B

Agent for Applicants

20/571180.1

INFORMATION DISCLOSURE EITATION IN AN APPLICATION (Use several sheets if necessary)  DEL 0 8 2003							oplication Number /787,325		
				Applicant Stuart A Fine et al.					
				Filing Date September 17, 1999			Group Art Unit 1617		
		12.	æ/	U	.S. PATENT DOCUMENTS				
EXAMINER INITIAL	DOCUMENT NUMBER AND DAT		3	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	Λl	5,962,030	10/05/199		Fine	424	646	11/05/1997	
	Λ2	6,203,819	03/20/2001		Fine	424	646	03/19/1999	
	A3 6,376,549 04/23/2			003	Fine et al	514	635	09/17/1998	
FOREIGN PATENT DOCUMENTS									
DOCUMENT NUMBER DATE				E	COUNTRY	CLASS	SUBCLASS	Translation YES NO	
		OTH	IER DO	CUN	1ENTS (Including Author, Title, Date, Pert	inent Pages Etc.)			
	CI	"Chromium picolinate for good health?," Biolifeplus.com, 'Online! 10/16/99, XP002135607, www.biolifeplus.com/library/chromium.html, retrieved on 4/5/00							
	C2	Bahadori et al., "Effects of Chromium Picolinate on Insulin Levels and Glucose Control in Obese Patients with Type - II Diabetes Mellitus," <i>Diabetes</i> , Abstract Book, 59 <sup>th</sup> Scientific Sessions, pp. A349 (1999)							
	СЗ	ChromeMate: Research Summary (1993)							
	C4	Salonen et al., "Increased risk of non-insulin dependent diabetes mellitus at low plasma vitamin E concentrations: a four year follow up study in men" <i>BMJ</i> 311, pp. 1124-1127 (1995)							
	C5	Diabetes Pro Health Inc., "Introducing A Nutritional Supplement Specifically Formulated For Adults With Diabetes & Pre-Diabetes" (1997)							
	C6	Verma et al., "Metformin improves cardiac function in isolated streptozotocin-diabetic rat hearts," American Journal of Physiology, (1994)							
	C7	Haupt et al., "Metformin and its role in the management of type-2-diabetes," <i>Medizinische Klinik</i> , Munich, (1997)							
	C8	Anderson et al., "Elevated intakes of supplemental chromium improve glucose and insulin variables in individuals with type 2 diabetes," <i>Diabetes</i> , Vol. 46, No. 11, pp. 1786-1791 (1997)							
	С9	Ziegler et al., "Treatment of symptomatic diabetic peripheral neuropathy with the anti-oxidant α-lipoic acid: A 3-week multicenter randomized controlled trial (Aladin Study)," Diabetes-Forschungsinstitut, (1995)							
	C10	Pote et al., "An antiatherogenic role for folic acid in experimental diabetes," Journal of Clinical Biochemistry and Nutrition, Vol. 18(3), pp. 157-164 (1995)							
	C11	Mark et al., "Hypoglycemic effects of the novel antidiabetic agent repaglinide in rats and dogs," British Journal of Pharmacology, Vol. 121(8), pp. 15497-1604 (1997)							
EXAMINER	,	<del></del>			DATE CONSID	DERED			
EXAMINER: conformance a	Initi Ind no	al if citation considered, ot considered. Include o	whether copy of thi	or not	citation is in conformance with MPEP § m with next communication to the applic	ant.		if not in	